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COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

**supplementing Regulation (EU) 2017/625 of the European Parliament and of the
Council with regard to requirements to be respected by consignments of certain animals
and goods intended for human consumption entering the Union**

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. LEGAL CONTEXT OF THIS DELEGATED REGULATION

Regulation (EU) 2017/625 of the European Parliament and of the Council¹ lays down rules for the performance of official controls and other control activities by the competent authorities of the Member States. It also sets out the requirements to be fulfilled for the entry into the EU of consignments of animals and goods from ‘third countries’ (i.e. countries outside the EU), and it empowers the Commission to adopt delegated acts concerning those requirements.

This Delegated Regulation supplements the requirements for the entry into the EU of consignments of certain foods intended for human consumption, laid down in (Article 125 of) Regulation (EU) 2017/625. These requirements are based on the risks that certain foods may pose to public health. Their purpose is to ensure that consignments of food from third countries comply with requirements laid down in EU legislation, or with requirements recognised to be at least equivalent to this legislation.

The requirements laid down in this Delegated Regulation are largely based on the rules already laid down in current EU legislation, in particular in the requirements of three legal acts:

- Chapter III on procedures concerning imports of Regulation (EC) No 854/2004 of the European Parliament and of the Council²;
- Article 48 on specific import requirements in Regulation No 882/2004 of the European Parliament and of the Council³. Both of these pieces of legislation are repealed by Regulation (EU) 2017/625;
- Commission Regulation (EU) 211/2013⁴.

Transitional measures are laid down for the entry into the Union of certain food until 31 December 2020] in accordance with Commission Regulation (EU) 2017/185⁵.

The requirements set out in this draft delegated regulation consist of a three-tiered system of guarantees consisting of the following requirements:

¹ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 60/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

² Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

³ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁴ Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 26).

⁵ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 29, 3.2.2017, p. 21).

- (a) requirements for the listing of third countries or regions thereof authorised for imports of food into the European Union. Third countries or regions in these third countries are included in those lists through an implementing regulation in accordance with Article 127 of Regulation (EU) 2017/625.
- (b) the requirement that consignments of certain animals and goods from third countries must be dispatched from, and obtained or prepared in establishments which comply with relevant requirements referred to in Article 1(2)(a) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto and listed in accordance with this Regulation.
- (c) the requirement that consignments be accompanied by appropriate official certification confirming their compliance with relevant requirements applicable in the EU.

Additional specific import requirements for bivalve molluscs, fishery products and composite products have also been included. The import requirements laid down in this delegated regulation take into account (as do the existing rules laid down in Regulation (EC) No 854/2004) the specific characteristics of certain products, for example, fishery products and molluscs. They also take into account the need for greater flexibility when certain products pose a lower level of risk to public and animal health.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE DELEGATED REGULATION

The Commission invited representatives of the European Parliament and of the Member States to attend expert-group meetings during the preparation of the draft delegated regulation.

In addition, private stakeholders' organisations were consulted as part of the Advisory Group on the Food Chain and Animal and Plant Health.

Third countries were informed by notification to the World Trade Organisation within the framework of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

Finally, before adopting this Delegated Regulation the Commission conducted open and transparent public consultations in accordance with the procedures laid down in the Inter-institutional Agreement on Better Law-Making⁶.

3. LEGAL BASIS OF THE DELEGATED REGULATION

This delegated regulation will be adopted pursuant to Article 126(1) of Regulation (EU) 2017/625. This initiative is necessary as Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004 of the European Parliament and of the Council with effect from 14 December 2019 and for certain products, it is necessary to establish requirements for their entry into the Union.

⁶ http://ec.europa.eu/smart-regulation/better_regulation/documents/iia_blm_final_en.pdf.

COMMISSION DELEGATED REGULATION (EU) .../...

of **XXX**

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements to be respected by consignments of certain animals and goods intended for human consumption entering the Union

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 60/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)⁷, and in particular Article 126(1) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States, including for the establishment of requirements to be fulfilled for the entry into the Union of consignments of animals and goods from third countries or regions thereof and official controls performed on such consignments that are intended for human consumption in order to ensure that they comply with Union legislation in the area of food and food safety in accordance with its Article 126 thereof.
- (2) Regulation (EU) 2017/625 provides a legal basis to supplement the requirements for entry into Union of with additional requirements for certain animals and goods. These additional requirements include guarantees concerning the verification of compliance with:
 - the measures to monitor substances and groups of residues in animals and goods intended for human consumption in accordance with Council Directive 96/23/EC⁸;

⁷ OJ L 95, 7.4.2017, p. 1.

⁸ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

- the rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in live animals and products of animal origin in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council⁹;
- the general principles and requirements governing food in general and food safety in particular at Union and national level in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council¹⁰;
- the general rules for food business operators on the hygiene of foodstuffs in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council¹¹;
- the specific rules on the hygiene of food of animal origin for food business operators in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council¹²; and,
- the specific rules on official controls and for action taken by the competent authorities in relation to production of products of animal origin intended for human consumption in accordance with Commission Delegated Regulation (EU) [SANTE/10193/2017]¹³ and Commission Implementing Regulation (EU) [SANTE/10194/2017]¹⁴.

Moreover, these additional requirements include guarantees given by the third country concerning establishments from which goods are exported to the Union referred to in recital 13.

- (3) Regulation (EC) No 854/2004¹⁵ laid down specific conditions for the entry into the Union of products of animal origin intended for human consumption, while Regulation (EC) No 882/2004¹⁶ laid down the general conditions for the entry into the Union of any food. Regulation (EU) 2017/625 lays down rules in areas currently covered by

⁹ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

¹⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

¹¹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

¹² Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

¹³ Commission Delegated Regulation (EU) ..., of .../... concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L ..., .../..., p. ...).

¹⁴ Commission Implementing Regulation (EU) of .../.... laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L ..., .../..., p. ...).

¹⁵ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

¹⁶ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

those two Regulations and it repeals them and replaces them with effect from 14 December 2019.

- (4) The requirements laid down in this Regulation should ensure a continuation of the requirements laid down in Regulations (EC) No 854/2004 and (EC) No 882/2004 to ensure a high level of protection of health and in order to avoid a disruption of the entry into the Union of consignments of certain animals and goods intended for human consumption. At the same time the experience gained in the application of the rules laid down in those two Regulations should be taken into account using a risk-based approach.
- (5) Regulation (EC) No 853/2004 lays down requirements for food business operators importing products of animal origin into the Union. Accordingly, the additional requirements laid down in this Regulation for official controls should be consistent with those already laid down in Regulation (EC) No 853/2004.
- (6) Commission Regulation (EU) 2017/185¹⁷ provides for derogations concerning public health requirements for the imports of certain products of animal origin (such as insects and reptile meat) and food containing both products of plant origin and processed products of animal origin (composite products) until 31 December 2020. In order to ensure a high level of protection of health, requirements for the entry into the Union of such products should also be laid down before the end of the transitional measures in order to verify of compliance with Union rules covering these products.
- (7) Insects are increasingly produced for human consumption. It should be ensured that imported insects comply with the Union requirements for food and food safety. The additional requirements laid down in this Regulation for the entry into the Union of consignments of products of animal origin should therefore also apply to insects. Since dead insects, parts of insects and processed insects are also subject to authorisation as novel food in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council¹⁸, certification of compliance with that Regulation should also be introduced as additional requirements for the entry into the Union of those products.
- (8) On 18 October 2007, the European Food Safety Authority adopted an Opinion on the public health risks involved in the human consumption of reptile meat¹⁹. A number of hazards such as *Salmonella* and *Trichinella* were identified. Requirements for the entry into the Union should include verification of compliance with the Union requirements to reduce the risk from these hazards in consignments of reptile meat.
- (9) The composition of composite products affects the physico-chemical characteristics of such foods, leading to different risks. For this reason, only consignments of composite products which comply with appropriate requirements, notably on the origin of the processed products of animal origin that compose such foods, the origin of the food itself, or the guarantees that accompany the consignments of composite products, should be authorised for enter into the Union. For composite products that pose a low

¹⁷ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and the Council (OJ L 29, 3.2.2017, p. 21).

¹⁸ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1.).

¹⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/578>

risk to human health, this Regulation should provide for derogations from checks at the border control posts.

- (10) When laying down requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption, reference should be made to the Combined Nomenclature codes in accordance with Council Regulation (EEC) No 2658/87²⁰ to clearly identify these goods and animals.
- (11) Consignments of certain animals and goods intended for human consumption should only be allowed to enter the Union, based on a risk analysis, when the third countries or regions thereof from which the foods originate can ensure compliance with the requirements on the safety of the food and they are duly listed in Commission Implementing Regulation (EU) [SANTE/10280/2018]²¹, adopted pursuant to Article 127(2) of Regulation (EU) 2017/625.
- (12) In addition to the requirements in Article 127(3) of Regulation (EU) 2017/625, specific requirements should be laid down for certain animals and goods intended for human consumption in order to provide guarantees as regards the efficiencies of official controls on food safety in third countries or regions thereof. Third countries or regions thereof should only appear on lists after evidence and guarantees have been provided that the animals and goods concerned from the third countries or regions thereof comply with Union requirements for the safety of food, or with requirements equivalent thereto, laid down in Directive 96/23/EC, Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EU) 2017/625, Delegated Regulation (EU) [SANTE/10193/2017] and Implementing Regulation (EU) [SANTE/10194/2017].
- (13) Consignments of certain goods intended for human consumption should only be allowed to enter the Union where those goods are dispatched from, and obtained or prepared in, establishments which appear on lists drawn up and kept up to date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission. In addition, in order to ensure compliance with Union food hygiene rules, or with rules which are at least equivalent thereto, it is appropriate to provide that when drawing up and updating the lists of such establishments referred to in Article 127(3)(e) of Regulation (EU) 2017/625, the third country should give the following additional guarantees to those referred to in Article 127(3)(e) (i) and (iv) of Regulation (EU) 2017/625:
 - establishments from which products of animal origin exported to the Union are dispatched from, and obtained or prepared in, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with relevant Union requirements, in particular those of Regulation (EC) No 853/2004, or with requirements which are at least equivalent thereto;
 - the establishment, where appropriate, only handles raw materials of animal origin that come from third countries with an approved residues monitoring

²⁰ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 739.1987, p. 1).

²¹ Commission Implementing Regulation (EU) of .././.... establishing lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption and amending Implementing Regulation (EU) 2016/759 as regards these lists (OJ L, .././....., p. ...).

plan for that product category in accordance with Directive 96/23/EC or from Member States;

- it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements which are at least equivalent thereto.
- (14) The Commission should make the aforementioned lists of establishments available to the public to ensure transparency for food business operators and consumers from which establishments such goods may enter the Union for placing on the market. With a view to ensure the effectiveness of these requirements, Member States should allow the import of consignments of such goods provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authority of the third starting with the date of publication by the Commission of the lists.
- (15) Such requirements concerning establishments should not be established in relation to goods intended for transit, since they represent a low risk from a food safety perspective and there is no placing on the market of animals and goods within the Union. In addition, such requirements should not be established for establishments carrying out only primary production activities, transport operations, storage of products of animal origin not requiring temperature-controlled storage conditions or production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.
- (16) Commission regulation (EU) No 210/2013²² requires the establishments producing sprouts to be approved by the competent authority in accordance with Article 6 of Regulation (EC) No 852/2004. In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, sprouts produced in these establishments should only be allowed entry to the Union if these establishments appear on lists drawn-up and updated in accordance with this Regulation.
- (17) In order to ensure compliance with Union food hygiene rules, or with rules at least equivalent thereto, products from establishments manufacturing fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine or collagen, should only be allowed entry to the Union if these establishments appear on lists drawn-up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission. In addition, the raw materials these products are manufactured from, should come from establishments (slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products) appearing on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission.
- (18) Consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods should only enter the Union from production areas in third countries or regions thereof that appear on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with specific requirements for these products laid down in

²² Commission regulation (EU° No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC° No 852/2004 of the European Parliament and of the Council (OJ L 68 12.3.2013, p. 24).

Regulation (EC) No 853/2004 and Implementing Regulation (EU) [SANTE/10194/2017], or with rules which are at least equivalent thereto. The publication of those lists should ensure transparency for food business operators and consumers from which production areas live bivalve molluscs, echinoderms, tunicates and marine gastropods may enter the Union.

- (19) Consignments of fishery products should only be allowed entry into the Union when the consignments are dispatched from, obtained or prepared in reefer, factory or freezer vessels flying the flag of a third country that appear on lists drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and which are published by the Commission, in order to ensure compliance with Union requirements, in particular with the specific requirements for fishery products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) [SANTE/10194/2017], or with rules recognised to be at least equivalent thereto. The publication of such lists should ensure transparency for food business operators and consumers as regards the vessels from which fishery products may enter the Union.
- (20) The conditions for entry into the Union of products of animal origin laid down in Regulation (EC) No 853/2004 do not apply to composite products. However, that Regulation requires the food business operators importing composite products to ensure that the processed products of animal origin contained in such foods satisfy the requirements laid down in that Regulation.
- (21) Based on the number of notifications received in the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002, consignments of certain animals and goods placed on the market for human consumption present an enhanced risk for non-compliance with Union requirements on food safety. Consignments of such animals and goods placed on the market for human consumption should therefore be subject to the individual certification of each consignment for entry into the Union for placing on the market. Certification of compliance with Union requirements may also contribute to reminding food business operators and the competent authorities of third countries and regions thereof of the applicable Union requirements. In the case of transit, the use of the current dedicated transit certificates with animal health attestation should remain.
- (22) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should also apply from that date. Transitional measures providing derogations from Regulations (EC) No 853/2004 and (EC) No 854/2004, concerning public health requirements for the imports of composite products have been extended in accordance with Commission Regulation (EU) [SANTE/.../2018]²³. The import requirements laid down in this Regulation should therefore apply from 20 April 2021 for composite products in order to ensure a smooth transition,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of certain animals and goods intended for

²³ Commission Regulation (EU) [SANTE/XXX/2018] (EU) .../... of XXX laying down transitional measures for the application of public health requirements of imports of food containing both products of plant origin and processed products of animal origin.

human consumption from third countries and regions thereof in order to ensure that they comply with the relevant requirements established by the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.

2. The following animals and goods fall outside the scope of this Regulation:
 - (a) Animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided at entry into the Union, this Regulation applies;
 - (b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.
3. The requirements referred to in paragraph 1 cover:
 - (a) the identification of animals and goods subject to the following requirements for entry into the Union apply:
 - (i) the requirement that those animals and goods shall come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625;
 - (ii) the requirement to be dispatched from, and obtained or prepared in, establishments which comply with relevant requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements which are at least equivalent thereto and which appear on lists drawn-up and updated in accordance with Article 127 (3) (e) of Regulation (EU) 2017/625 and published by the Commission, in accordance with Article 126(2)(b) of Regulation (EU) 2017/625;
 - (iii) the requirement that each consignment of animals and goods be accompanied by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625, such as private attestation, in accordance with Article 126(2)(c) of Regulation (EU) 2017/625;
 - (b) requirements for entry into the Union of certain animals and goods from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;
 - (c) requirements that consignments of certain goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with relevant requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements which are at least equivalent thereto and which appear on lists drawn-up and updated in accordance with Article 127 (3) (e) of Regulation (EU) 2017/625 and published by the Commission, in accordance with Article 126(2)(b) of Regulation (EU) 2017/625;
 - (d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:
 - (i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine or collagen;
 - (ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;

- (iii) fishery products;
- (iv) composite products.
- (e) additional requirements for the official certificates, official attestations and private attestations that shall accompany certain animals and goods for entry into the Union.

Article 2 **Definitions**

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'equivalent' means equivalent as defined in point (1)(e) of Article 2 of Regulation (EC) No 852/2004;
- (2) 'placing on the market' means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
- (3) 'establishment' means establishment as defined in Article 2(c) of Regulation (EC) No 852/2004;
- (4) 'private attestation' means an attestation signed by the importing food business operator;
- (5) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (6) 'minced meat' means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;
- (7) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (8) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'mechanically separated meat' means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
- (10) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;
- (11) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (12) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (13) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (14) 'composite product' means food containing both products of plant origin and processed products of animal origin;
- (15) 'reptiles' means animals belonging to the species *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon Lepidus*, *Python reticulatus*, *Python molurus bivittatus* and *Pelodiscus sinensis*;
- (16) 'reptile meat' means edible parts derived from farmed reptiles, either fresh or processed;

- (17) 'insects' means food consisting of, isolated from or produced from insects or their parts which are authorised in accordance with Regulation (EU) 2015/2283 and listed in the Union list of novel foods, or any live stadia of insects intended for direct or indirect human consumption;
- (18) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013²⁴;
- (19) 'primary production' means primary production as defined in point (17) of Article 3 of Regulation (EC) No 178/2002;
- (20) 'slaughterhouse' means slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
- (21) 'game-handling establishment' means game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
- (22) 'cutting plant' means cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
- (23) 'production area' means production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
- (24) 'factory vessel' means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (25) 'freezing vessel' means freezing vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;
- (26) 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers;
- (27) 'food business operator' means food business operator as defined in point (3) of Article 3 of Regulation (EC) No 178/2002.

Article 3

Animals and goods which are required to come from third countries or regions included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625

Consignments of the following animals and goods shall enter the Union only from a third country or region thereof included in the corresponding list for those animals and goods laid down in Implementing Regulation (EU) [SANTE/10280/2018]:

- (a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, for which Combined Nomenclature codes ('CN codes') have been laid down in Sections 2 to 5, 15 and 16, and Harmonised System codes ('HS codes') 1702, 1806, 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part II of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00;

²⁴ Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

Article 4

Additional requirements for entry into the Union of certain animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2)(a) of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for animals and goods referred to in Article 3:

- (a) the legislation of the third country on:
 - (i) the production of food of animal origin;
 - (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
 - (iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;
- (b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;
- (c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;
- (d) when available, the results of controls carried out by the Commission in the third country related to other animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;
- (e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;
- (f) the existence, implementation and communication of a residue control programme approved by the Commission when applicable, in accordance with Directive 96/23/EC.

Article 5

Requirements for entry into the Union of certain goods from a third country in relation to establishments

1. Consignments of the following goods shall only enter the Union where those consignments are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3)(e) (EU) 2017/625 and published by the Commission on its website:
 - (a) products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, and for which CN codes have been laid down in Sections 2 to 5, 15 and 16, and 'HS codes' 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102,

4103 and 4110 of Part II of Annex I to Council Regulation (EEC) No 2658/87, when these products are intended for human consumption;

(b) sprouts referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90.

2. Establishments referred to in paragraph 1 may be placed on the lists referred to in Article 127(3)(e) of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3)(e) (i) and (iv) of Regulation (EU) 2017/625, the third country gives the following guarantees:

(a) such establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with relevant Union requirements, in particular those of Regulation (EC) No 853/2004, or with requirements which are at least equivalent thereto;

(b) the establishment, where appropriate, only handles raw materials of animal origin that come from third countries with an approved residues monitoring plan for that product category in accordance with Directive 96/23/EC or from Member States;

(c) it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements which are at least equivalent thereto.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country in accordance with Article 127(3)(e)(iii) of Regulation (EU) 2017/625 and shall publish such lists on its website.

Member States shall allow the import of the consignments referred to in paragraph 1 provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authority of the third starting with the date of publication by the Commission of the lists referred to in paragraph 1.

Paragraph 3 and 4 shall apply also to the areas covered by Articles 7, 8 and 10.

Article 6

Establishments not subject to the requirements of Article 5(1)

The requirements laid down in Article 5 shall not apply to establishments that only carry out the following activities:

(a) only primary production;

(b) only transport operations; or,

(c) storage of products of animal origin not requiring temperature-controlled storage conditions;

(d) production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 and referred to by the CN codes under the heading of 2833, ex 3913, 2930, ex 2932, 3507 or 3503.

Article 7

Requirements for consignments of fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for gelatine or collagen

Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products, appearing on lists of establishments drawn up and kept up-to-date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission on its website or in establishments approved in accordance with Article 4(2) of Regulation (EC) No 853/2004:

- (a) fresh meat,
- (b) minced meat,
- (c) meat preparations,
- (d) meat products and mechanically separated meat, and
- (e) raw materials intended for the production of gelatine or collagen referred to respectively in point 4(a) of Chapter I of Section XIV and in point 4(a) of Chapter I of section XV of Annex III to Regulation (EC) No 853/2004.

Article 8

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 6, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down in heading 0307 of Part II of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission on its website.
2. The following products may enter the Union from production areas which have not been classified by the competent authority in the third country in accordance with Article 18(6) of Regulation (EU) 2017/625:
 - (a) Pectinidae, except where data from official monitoring programmes as established in Article 58 of Implementing Regulation (EU) [SANTE/10194/2017] enable the competent authority to classify fishing grounds as set out in point (2) Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004;
 - (b) marine gastropods that are not filter feeders and *Holothuroidea* that are not filter feeders.

Article 9

Listing of production areas

1. Before the lists referred to in Article 8(1) are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation [SANTE/10194/2017] on the classification and control of production areas.

The Commission shall carry out an on-the-spot control visit before it draws up such lists.

2. Once lists referred to in Article 8(1) are drawn up, and when the competent Authorities of the third country offer sufficient guarantees on the management and controls of production areas under their responsibility, the on-the-spot Union control visit need not to be carried out prior to the addition of a production area to an existing list established in accordance with Article 5.

Article 10

Special requirements for fishery products

1. Consignments of fishery products for which CN codes have been laid down in headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1603, 1604, 1605 or 2106 of Part II of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been:
 - (a) obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel, or
 - (b) stored in a coldstore or a reefer vesselthat appear on a list drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission on its website.
2. By way of derogation from Article 127(3)(e)(iv) of Regulation (EU) 2017/625, a vessel may also be included on the lists of establishments provided that the competent authority of the third country the flag of which the vessel is flying and the competent authority of another third country to which the former competent authority has delegated responsibility for the inspection of the vessel concerned provide the Commission with a joint communication stating that all four of the following requirements are met:
 - (a) both third countries appear on the list of third countries, drawn up in accordance with Article 3, from which entry into the Union of fisheries products is permitted;
 - (b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that third country;
 - (c) the competent authority has inspected the vessel and has declared that it complies with Union requirement;
 - (d) the competent authority has declared that it will regularly inspect the vessel to ensure that it continues to comply with Union requirements.
3. By way of derogation from Article 127(3)(e)(iv) of Regulation (EU) 2017/625, a vessel may be included on the lists of establishments on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of a Member State, to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, if all three of the following requirements are met:
 - (a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that Member State;
 - (b) the competent authority of that Member State has inspected the vessel and has declared that it complies with Union requirements;

- (c) the competent authority of that Member State has declared that it will regularly inspect the vessel to ensure that it continues to comply with Union requirements.
4. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate referred to in Article 12(1)(a) may be signed by the captain.

Article 11

Requirements for consignments of composite products

1. Consignments of composite products referred to by the HS codes 1601, 1602, 1603, 1604, 1605, 1901, 1902, 1905, 2004, 2005, 2103, 2104, 2105, 2106 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 4 or in establishments located in Member States.
2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter into the Union, subject to compliance with the following rules:
- (a) Composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised to export each processed product of animal origin contained in the final product to the EU, pursuant to Commission Decision (EU) 2007/777²⁵, Commission Regulation (EU) 605/2010²⁶, Commission Decision (EU) 2006/766²⁷ and Commission Regulation (EU) 798/2008²⁸;
- (b) Composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures containing any quantity of processed meat shall originate from third countries or regions thereof authorised to export to the Union the meat products contained in the composite product pursuant to Commission Decision 2007/777/EC and Decision 2011/163/EU²⁹;
- (c) Composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and contain processed

²⁵ Commission Decision 2007/777/EC laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

²⁶ Commission Regulation laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption (O.J. L175, 10.7.2010. p. 1).

²⁷ Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53–57).

²⁸ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

²⁹ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

products of animal origin other than processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 shall originate from third countries or regions thereof authorised to export meat products, dairy products, colostrum-based products, fishery products or egg products to the Union on the basis of the EU animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Decision (EU) 2007/777, Commission Regulation (EU) 605/2010, Commission Decision (EU) 2006/766 and Commission Regulation (EU) 798/2008, and in the annex to Decision 2011/163 on the basis of an approved residues control plan approved in accordance with Directive 96/23/EC.

Article 12

Official certificates

1. Each consignment of the following products shall enter the Union only where those consignments are accompanied by an official certificate:
 - (a) products of animal origin for which CN codes have been laid down in Chapters Sections 2 to 5, 15, and 16, and HS codes 1506, 1521, 1601, 1602, 1603, 1604, 1605, 2102, 2103, 2105, 2106, 2202, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part II of Annex I to Council Regulation (EEC) No 2658/87, when these products are intended for human consumption;
 - (b) live insects referred to by the CN codes 0106 49 00;
 - (c) sprouts and seeds thereof intended for the production of sprouts and referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0712 34, 0712 35, 0713 39, 0713 40, 0712 50, 0712 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90.
2. The official certificates referred to in paragraph 1 shall certify that the products comply with:
 - (a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions that are equivalent to those requirements;
 - (b) any specific requirements for entry into the Union set out in this Regulation.
3. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.
4. The official certificate for sprouts and seeds intended for sprouting referred to in paragraph 1(c), shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

Article 13

Private attestation

1. A private attestation, prepared and signed by the importing food business operator, shall accompany the consignments of composite products as referred to in point 2(c) of Article 11 confirming that the consignments comply with the relevant requirements referred to in Article 126(1) of Regulation (EU) 2017/625.

2. By way of derogation to paragraph 1, for the products exempted from official controls at border control posts, in accordance with Article 48(h) of Regulation (EU) 2017/625, the private attestation shall accompany the products at the time of the placing on the market.
3. The private attestation referred to in paragraph 1 shall account for the traceability of the consignment and shall include information regarding the consignor and consignee of the imported goods.
4. The private attestation referred to in paragraph 1 shall attest that:
 - (a) the third country or regions thereof producing the composite product is authorised to export at least one of the following category of product of animal origin to the Union:
 - (i) meat products;
 - (ii) dairy products, colostrum-based products;
 - (iii) fishery products;
 - (iv) egg products;
 - (b) the establishment producing the composite products fulfils hygiene standards equivalent to those required by Regulation (EC) No 852/2004;
 - (c) the product does not need to be stored or transported under controlled temperature;
 - (d) the processed products of animal origin contained in the composite product originate from third countries or regions thereof authorised to export each processed product of animal origin to the Union, or from the Union, and are sourced from listed establishment(s). The approval number of the establishment(s) shall be indicated by the importing food business operator. The list of products of plant origin and processed products of animal origin contained in the composite products shall be indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite product;
 - (e) the processed products of animal origin used in the composite product have undergone at least the treatment provided for in the Union animal health import legislation for those products pursuant to Commission Decision (EU) 2007/777 and Commission Regulation (EU) 605/2010 or a higher treatment and a brief description must be provided of any processes undergone and temperatures applied to the product.

Article 14

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 December 2019. However, the requirements laid down in Articles 11, (13)(1) and 13(2) shall only apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

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